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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,579	12/18/2001	Carl Johan Friddle	LEX-0274-USA	2417

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,579	FRIDDLE ET AL	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 12/30/04 has been entered.

2. Applicant's arguments filed 12/30/04 have been fully considered but they are not persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 9-10 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons made of record in Paper No: 20040624, and as follows.

In contrast to Applicant's assertions on page 2 of the response, owning a human host that had undergone gene therapy is non-statutory. *In arguendo*, page 19 alternatively states "[a]nimals of *any species*, including, *but not limited to*..." [emphasis added], which further does not exclude human transgenes. Second, Applicant is reminded that each application is examined according to its own merits, whether or not "**thousands** of patents directed simply to 'host cells'" have been issued. Thus, Applicant's arguments are not on point.

It is noted that Applicant has chosen to disregard the Examiner's suggestion that amending the claims to "an isolated host cell" would obviate this particular rejection.

5. Claims 2-4 & 8-10 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper No: 20040624, and as follows.

Applicant argues on pages 2-13 of the response that the current pending lack of utility under 35 U.S.C. 101 is "improper", that "the presently claimed sequence shares greater than 99% identity at the amino acid level over nearly the entire length of SEQ ID NO: 5 with a sequence that is present in the leading scientific repository for biological sequence data (GenBank)...", and cites *Raytheon v. Roper, In re Gottlieb, In re Malachowski, Hoffman v. Klaus, In re Brana, Carl Zeiss Stiftung v. Renishaw PLC, In re Langer, Juicy Whip Inc. v. Orange Bang Inc., Brenner v. Manson, Brooktree Corp. v. Advanced Micro Devices, Inc., Cross v. Iizuka, State Street Bank & Trust Co. v. Signature Financial Group Inc., Diamond vs. Chakrabarty,* along with the enablement decisions of *In re Wands, In re Angstadt and Griffin, Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.,* and *In re Marzocchi.* In contrast to Applicant' assertions, the issue is that NHP stands for "*novel* human proteins *described for the first time*" [emphasis added] (pg. 2), in which Applicant appears to confuse a putative potassium channel "domain" with what constitutes a whole and functional protein, if such protein's function is later discovered. In other words, many different types of potassium channels exist in the art (e.g., see Exhibit B). In contrast, no where in the specification is it described or contemplated that the encoded protein of SEQ ID NO: 5 is a known and specific "potassium channel" at the time of filing the instant application (i.e., as it relates to beginning to establish a "specific" use). Accordingly, Applicant's reference to Exhibits B & C concerning the teachings of Yi et al. and Strang et al. as

establishing a "well established utility" for the instant invention is misplaced, because Yi et al. alternatively state in their abstract that "potassium channels [are] an *extraordinary diverse group* of ion channels [emphasis added]". In other words, the mere mention of a putative potassium channel "domain" in Applicant's *response* cannot be **specific** or "well established", by definition, because many different types of potassium channels with their own unique characteristics exist in the art. Accordingly, Applicant mischaracterizes what the art and GenBank sequences actually teach.

Second, the issue remains that *many* genes are potentially useful "in forensic biology", provided the polymorphism can be detected with an appropriate restriction enzyme that specifically cuts at the disclosed polymorphism. However, the possible existence of a potential polymorphism by itself does not constitute a "real world" utility, without requiring further experimentation by others to discover such after-the-fact (i.e., as it relates to identifying a given population with a distinguishable characteristic, which the specification fails to disclose). Therefore, in contrast to Applicant's assertions, "the present situation [*does not*] **exactly** track Example 10 of the Revised Interim Utility Guidelines Training Materials" because Applicant's specification itself fails to describe any known "*specific*" assayable activity with a known "use" that distinguishes it from any different and random nucleic acid. In other words, the mere mention of a "polymorphism" in a vacuum teaches nothing and, therefore, has no "use", by definition.

In summary, no use for any of HNP polynucleotides are reasonably known within the art nor reasonably disclosed within the specification at the time of filing the instant application, especially when the mere mention of "forensic biology" on page 3 of the specification does not

reasonably extrapolate to knowing the relationship between a putative polymorphism and what constitutes a "real world" forensic analysis for a given population. Clearly, not a single distinguishable human subpopulation, or restriction enzyme that could be used to detect any putative polymorphism, is contemplated within the instant specification at the time of filing Applicant's invention. In other words, "until such a polymorphism is *actually identified and described*, such a likelihood [for use in forensic analysis] is meaningless" [emphasis added].

Applicant then argues that " 'DNA chips' clearly have utility", and that the "present sequences are specific markers of human chromosome 7", which also has nothing to do with establishing a "specific" utility for the polynucleotide of SEQ ID NO: 5, because the "utility" for DNA chips is not based upon the existence of the polynucleotide of SEQ ID NO: 5, and because many different nucleotide sequences can be "markers" of chromosome 7, in which "localizing the specific region of human chromosome 7 that contains the gene encoding the given polynucleotide (*sic*) [with no known utility] ... " does not reasonably establish a "*specific*" and distinguishable utility for the polynucleotide of SEQ ID NO: 5. Likewise, an invitation for others to discover a "real world"/ "substantial utility" for the instant invention "for the discovery of [unknown and undescribed] drugs that are associated with [unknown and undescribed] human diseases" does not reasonably establish "substantial utility", by definition. In other words, Applicant's arguments concerning DNA chips, "any other nucleic acid sequences", "other nucleic acid sequences", "every nucleic acid", etc. are flawed, because they do not address what *specific* and distinguishable "use" exists for the polynucleotide of SEQ ID NO: 5, which in contrast to Applicant's assertions, clearly has not been "biologically validated", for the reasons indicated above, and for the reasons previously made of record.

Accordingly, because the proposed and prophetic generic uses of the polynucleotide of SEQ ID NO: 5 simply are starting points for further research and investigation into potential and practical uses of the polynucleotide of SEQ ID NO: 5, the instant claims have no specific nor substantial utility, consistent with that held by the court in Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct, 1966):

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Thus, Applicant's arguments that "holding Applicants to a different standard of utility would be arbitrary and capricious, and like other clear violations of due process, cannot stand" is clearly misplaced, and has no merit. Again, see the Utility Guidelines in MPEP 2107.

6. Claims 2-4 & 8-10 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper No: 20040624, and as follows.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
April 7, 2005

ROBERT C. HAYES, PH.D.
PATENT EXAMINER